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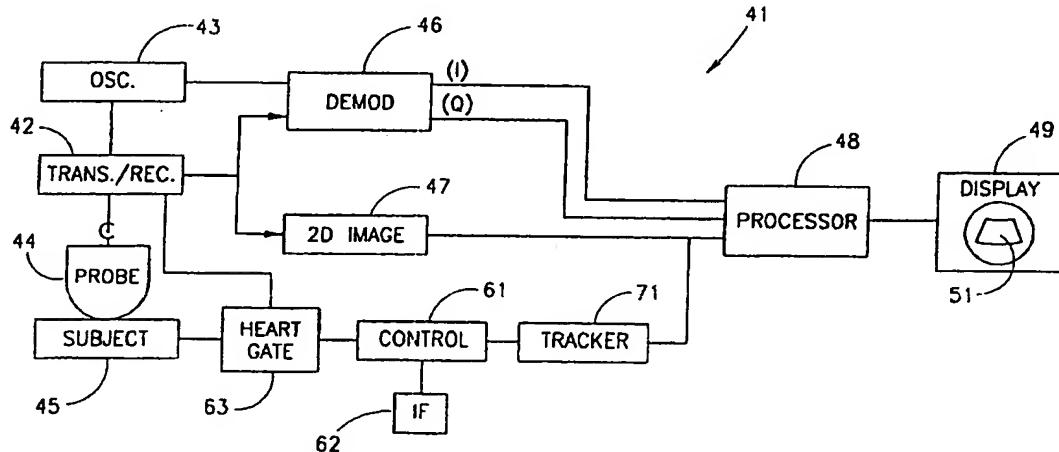
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(57) Abstract

A method for measurement of blood velocity in coronary blood vessels comprising: determining a time period at which the heart is relatively stationary; and determining the velocity of blood at one or more points in one or more coronary blood vessels utilizing ultrasound based method during said determined time period.

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CORONARY STENOSIS MEASUREMENTSFIELD OF THE INVENTION

The present invention relates to ultrasonic diagnostic imaging systems, and more particularly to such systems which are capable of performing measurements of stenosis in 5 coronaries using Doppler ultrasound techniques.

BACKGROUND OF THE INVENTION

Diagnostic ultrasound imaging systems provide a comprehensive evaluation of the subject's health condition. The efficacy of ultrasound techniques has resulted in wide-spread acceptance of ultrasound imaging diagnosis by both patients and physicians. In general, 10 diagnostic ultrasound imaging systems generate images of anatomical structures within the patient by transmitting ultra-high frequency sound waves (typically in the order of 3.0 to 10.0 MHz) and then analyzing the waves reflected from internal structures in the body. The most widely used ultrasonic diagnostic systems display structural information of organs in the form 15 of two-dimensional images of selected cross sections of an organ being examined. These images are widely known as "sector scans". Typically, the ultrasound is swept across the organ in the form of a "cross sectional scan". The scan is ordinarily performed in real time so that the dynamics of anatomical structures can be visualized.

Some presently available ultrasound systems also provide blood-flow information in addition to the anatomical information. The blood-flow information is provided by utilizing the 20 Doppler principle. The Doppler principle is implemented by generating a beam comprising pulses of ultrasonic energy that are directed toward a blood vessel in which blood flow information is desired. The moving blood cells in the blood vessel reflect the ultrasound energy and either increase or decrease the frequency of the reflected energy depending on the direction 25 of the blood flow relative to the imager. The magnitude of the frequency shift and the direction of the frequency shift are detected so that the velocity and the direction of the blood flow may be ascertained. Accordingly, using the Doppler principle it is well known to determine the velocity of the blood flowing in blood vessels at relatively precise locations.

However, until the present invention, it has not been feasible to use such systems to measure the velocity of the blood in the coronaries i.e. blood vessels attached to the heart. The 30 movement of the heart muscle throughout the heart's pumping action has prevented the use of Doppler for determining the velocity flow of the blood in the coronary blood vessels. It is well known that the coronaries are attached to and external to the heart muscle. Thus the movement of the heart muscle adversely affects any measured movement of blood in the coronaries by

ultrasound Doppler techniques. The increase or decrease of the echo frequency is influenced by the muscle movement as well as by the blood flow velocity. The muscle movement makes it difficult if not impossible to "filter" out the blood flow measurement from the measurements of the muscle movement.

5 Among other things, blood flow velocity can be used to determine a stenotic condition of blood vessels. A sharp increase in the flow velocity at a specific location on the blood vessel is a strong indication of a stenotic condition, i.e., that plaque has built up on the interior walls of the blood vessel decreasing the cross sectional area of the affected blood vessel.

Accordingly, until now, stenosis determinations in the coronaries are generally made by
10 using other imaging modalities. Digital subtraction angiography is a preferred method. More recently, stenosis measurements have been made using magnetic resonance imaging systems and/or computerized tomographic x-ray systems.

There are serious difficulties in using any of the other modalities for stenosis measurements. The digital subtraction angiographic systems require the patient to be subjected
15 to contrast material that is injected in the bloodstream. This invasive procedure has resulted in serious impairments to approximately 2% of the patients subjected to the procedure.

The computerized tomographic x-ray systems subjects the patients to x-ray radiation. In addition, CT systems are large and bulky and certainly not generally available in a doctors office. Thus a special trip to a radiation center or hospital is necessary for undertaking stenosis
20 examinations by computerized tomography.

The same negative aspects with regard to the size of the magnetic resonance imaging systems and their absence in doctors' offices applies to MRI systems used for measuring vascular conditions.

Finally, each of these available alternatives utilizes expensive equipment which is not
25 generally available, for example in a physician's office for routine examination. Thus, even when such systems are used they can not easily be used to monitor changes in the patient's condition.

Accordingly, those skilled in the art have been searching for ways and means to arrive at a stenosis examination of coronaries using ultrasound techniques. If ultrasound could be
30 used for determining coronary stenosis, the examination could be performed in the doctors office with the least amount of inconvenience and danger to the patient.

SUMMARY OF THE INVENTION

A first aspect of the present invention is concerned with the determination of the velocity of blood in moving blood vessels, especially in coronary blood vessels.

In a preferred embodiment of the invention one or more of a number of features are 5 present in order to allow for such measurement. For example, in preferred embodiments of the invention, the velocity measurements are made when the heart is substantially stationary.

Immediately before the start of the diastolic or the systolic movement of the heart, i.e. the usual rhythmic contraction of the heart, the heart muscle is almost completely at rest. Accordingly, preferred embodiments of the invention include temporal gating, so the Doppler 10 data acquisition will be performed during this time period of lack of motion of the heart muscle. The gating is based either on the patients on-line ECG or on the analysis of the Doppler signal itself. With the Doppler measurement made during the period that the heart muscle is at relative rest, it is possible to accurately measure the velocity of the blood in the coronaries.

15 In a preferred embodiment of the invention the velocity is determined only within a region of interest. This reduces the amount of data which is acquired so that the data can be acquired a very short period, for example during the short periods when the heart is generally at rest.

20 Preferably, the velocity is determined only at a plurality of sample points at which the coronaries are present. This further reduces the amount of data which must be acquired.

A second aspect of the invention is concerned with the determination of the magnitude of a coronary stenosis.

25 In a preferred embodiment of the invention the stenosis is measured by determining the velocity at one or more positions upstream and/or downstream of the stenosis and within the stenosis. The percent stenosis can then be determined from the ratio of the velocities of the blood within and outside of the stenosis. In general it is preferable to utilize velocities of the blood both upstream and downstream of the stenosis, however, under some circumstances, such as for a stenosis at or near a branch point (where only upstream values will normally be used) or for relatively unlocalized stenosis, this may not be feasible. In a preferred embodiment 30 of the invention the method of determining the velocity of the first aspect is utilized in finding the stenosis.

In a preferred embodiment of the invention, a plurality of sector scans is acquired, preferably when the heart is generally stationary. The position of the coronaries is determined

and the velocity is determined in each sector scan for the various coronary arteries. From this information, the position of a stenosis is determined and the velocity at the stenosis and at a one or more positions up or down stream of the stenosis is measured. The percent stenosis is determined from the ratio of the velocities. If there is stenosis, then there will be a marked
5 increase in the velocity of blood flow at the areas of stenosis in the coronaries. Thus by proper gating and Doppler measurements, the velocity of the blood taken at different axial points of the coronary, determines whether or not there is stenosis in the coronaries. Accordingly, a plurality of planar "cuts" are preferably taken of the heart and Doppler measurements are provided at the coronaries immediately prior to the systolic contraction. The area of interest is
10 divided into a multitude of sample volumes and multiple Doppler measurements are simultaneously accomplished to identify the coronaries and to make the velocity measurements at the coronaries in the image plane. The velocity measurements are, in a preferred embodiment of the invention, made in accordance with the system of U.S. patent 5,419,332 although other methods of blood velocity measurement known in the art may be
15 used in the practice of the invention. The contents of that patent is hereby incorporated by reference in this disclosure.

The "rest" time of the heart muscle is in the order of 100-200 msec. This is a sufficient time period in order to obtain sufficient data for a spectral Doppler image and especially with the use of multiple gates to simultaneously monitor a plurality of coronaries. Alternatively, this
20 time can be lengthened using certain medications.

There is thus provided, in accordance with a preferred embodiment of the invention a method for measurement of blood velocity in coronary blood vessels comprising:
determining a time period at which the heart is relatively stationary; and
determining the velocity of blood at one or more points in one or more coronary blood
25 vessels utilizing ultrasound based method during said determined time period.

Preferably, the ultrasound based method is a non-invasive method. Preferably, the method utilizes Doppler ultrasound for determining the velocity of the blood.

Preferably, determining a time period at which the heart is relatively stationary comprises utilizing an ECG measurement. Alternatively, determining a time period at which
30 the heart is relatively stationary comprises utilizing a Doppler ultrasound measurement.

In a preferred embodiment of the invention, the time period at which the heart is relatively stationary is the time period immediately prior to systole. Alternatively or additionally, the time period at which the heart is relatively stationary comprises the time

period immediately prior to systole. Preferably, the ultrasound system is gated to acquire data only during said time period at which the heart is relatively stationary.

A preferred embodiment of the invention includes:

transmitting ultrasound signals along at least one line, said at least one line intersecting a
5 point at which a coronary is located; and

locating said intersection point along each of the lines at the coronaries and determining the velocity of blood flow at the intersection point based on signals received from the blood in the coronaries.

There is further provided, in accordance with a preferred embodiment of the invention,
10 a method for measurement of stenosis in a coronary blood vessel comprising:

determining the velocity of the blood at the location of the stenosis utilizing ultrasound;
determining the velocity of the blood at one or more points in the vessel upstream and/or downstream of the stenosis utilizing ultrasound; and

15 computing the stenosis from the measured velocity at the stenosis and away from the stenosis.

Preferably, the velocity of the blood is measured according to one of the methods described above.

In one preferred embodiment of the invention, the location of a stenosis is determined prior to making said velocity measurements. Alternatively, the location of a stenosis is
20 determined based on said velocity measurements.

In a preferred embodiment of the invention, the method includes:

scanning the heart with ultrasound;

acquiring a plurality of ultrasound sector scan images of the heart at different locations in the heart;

25 examining each of the sector scan images using spectral Doppler signals to locate multiple coronaries;

gating the spectral Doppler signals to occur when the heart is at relative rest; and

determining the velocity of blood flow in the coronaries in each of the sector scan images by using the spectral Doppler signals.

30 Preferably, the method includes:

locating multiple coronaries in each of the sectors;

acquiring as much velocity information as possible during the gating period;

moving to the next sector to locate the multiple coronaries and to determine as much blood velocity information as possible during the gating period; and

returning to each of the sectors to complete the determination of the velocity information as necessary.

5 In a preferred embodiment of the invention the method includes determining the velocity of blood flow in each coronary in each sector before moving on to the next sector for measurements.

In a preferred embodiment of the invention, examining each of the sector scan images to locate coronaries includes:

10 traversing selected sectors by a plurality of beams for determining where along each of the beams multiple coronaries are located; and

simultaneously Doppler scanning each of the multiple coronaries in parallel to provide the blood flow velocity information in parallel with the sector scan.

15 Preferably, the method includes preventing misalignment between the sector scan images and flow images. Preferably, preventing misalignment includes the simultaneous generation of both the sector scan images and the Doppler images.

In a preferred embodiment of the invention, preventing misalignment comprises:

projecting a tracking element onto the coronaries, and

locking the tracking element onto the coronaries in the sector scan images.

20 Preferably, locking comprises using a TV tracker.

There is further provided, in accordance with a preferred embodiment of the invention, apparatus for measurement of blood velocity in coronary blood vessels comprising:

a controller which determines a time period at which the heart is relatively stationary; and

25 an ultrasonic measurement system, preferably, non-invasive, preferably Doppler, which determines the velocity of blood at one or more points in one or more coronary blood vessels during said determined time period.

30 In a preferred embodiment of the invention the controller comprises an ECG monitor which supplies electrical signals indicative of the motion of the heart. Preferably, the controller utilizes a Doppler ultrasound measurement in determining the time period.

In a preferred embodiment of the invention, the time period at which the heart is relatively stationary is the time period immediately prior to systole. Alternatively or additionally, the time period at which the heart is relatively stationary comprises the time

period immediately prior to systole. Preferably, the ultrasound system is gated to acquire data only during said time period at which the heart is relatively stationary.

In a preferred embodiment of the invention:

5 said ultrasonic measurement system transmits ultrasound signals along at least one line which intersects a point at which a coronary is located; and

 said controller locates said intersection point along each of the lines at the coronaries and determines the velocity of blood flow at the intersection point based on signals received from the blood in the coronaries.

10 There is further provided, in accordance with a preferred embodiment of the invention, apparatus for measurement of stenosis in a coronary blood vessel comprising:

 an ultrasonic measurement system which measures the velocity of the blood at the location of the stenosis and determines the velocity of the blood at one or more points in the vessel upstream and/or downstream of the stenosis; and

15 a controller which computes the severity of the stenosis from the measured velocity at the stenosis and away from the stenosis.

 Preferably the ultrasonic measurement system and the controller comprise the apparatus described above.

 Preferably, the ultrasonic measurement system and the controller utilize a method for determining stenosis as described above.

20 **BRIEF DESCRIPTION OF THE DRAWINGS**

The above mentioned and other objects and features of the present invention will be best understood when considered in the light of the following description of a preferred embodiment of the present invention, wherein:

25 Fig. 1 is a pictorial representation of the heart with coronaries at or slightly below the surface thereof;

 Fig. 2 is a sectional view of a coronary having a build-up of plaque therein causing stenosis;

30 Fig. 3 is a pictorial view of the heart with a plurality of sectional cuts there through made using an ultrasonic probe placed adjacent to the patient's body and varying the angle of the probe to provide the multiple sectors scans;

 Fig. 4 is a plan view of a single one of the sectional scans showing a coronary approximately perpendicular to the plane;

Fig. 5 graphically shows the velocity of the blood and corresponding Doppler shift through the heart cycle period;

Fig. 6 shows schematically the velocity of the blood in a blood vessel upstream of the stenosis, downstream of the stenosis and at the stenotic portion of the blood vessel; and

5 Fig. 7 is a block diagram of the preferred embodiment of the ultrasound system used to determine the velocity of blood in different axial sections of the coronaries.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

As indicated in the pictorial showing of the heart 11 in Fig. 1, there is more than one coronary at the surface of the heart. By way of example, two coronaries 12 and 13 are shown in
10 Fig. 1. The heart muscle is a pump that is almost always in motion as it goes through the diastolic and systolic movements.

As is well known, blood vessels tend to accumulate plaque on their inner walls which decreases their diameter and significantly reduces blood flow. This condition is known as stenosis.

15 Fig. 2 shows a blood vessel 14 having walls 16 and 17 of an initial thickness; but, having plaque 18 built up on the walls to diminish the inner diameter of the blood vessel. It is an object of the present invention to determine the degree of the stenosis. Stenosis can be determined and is determined in the instant case by measuring the velocity of the blood as it passes through different cross sectional areas in the blood vessel. As the plaque builds up, the
20 cross sectional area through which the blood flow diminishes, the velocity of the blood in the restricted area (indicated by arrow 19) increases according to the Bernoulli theorem. Thus an anomalous increase in velocity between two lower velocity portions in a blood vessel is a strong indication of stenosis. The amount of increase of the velocity is determinative of the relative blockage of the blood vessel by the plaque.

25 Fig. 3 shows an ultrasound array transducer 21 mounted external to and juxtaposed to the body of the patient. During the scanning, the transducer is moved to change the angle at which it transmits ultrasonic beams into the patient. In this manner, a plurality of sector scans shown as sector scans a, b, c, d, e and f by way of example are obtained. An individual sector scan section d, for example, is shown at Fig. 4, which is described in detail below. It is
30 important, of course, that the complete heart be scanned so that the coronary scan sectors show any difference in blood flow velocity between a section, such as the section indicated by the dashed line at 23 in Fig. 2 and a section indicated at dashed line 24 in Fig. 2.

In one preferred embodiment of the invention the positions of the stenosis is determined, at least approximately, prior to the scanning. In a second preferred embodiment of the invention the position of a stenosis is determined from the velocity measurements themselves, for example by graphing the measured velocities along a coronary vessel and 5 determining the position of a stenosis from an anomalous increase in velocity.

The actual window of time for making the scan and acquiring data is approximately 50-200 milliseconds which is the time during which the heart is almost stationary. That amount of time surprisingly proves sufficient, since only the determination of velocity is required. If sufficient data is not acquired during the first heart scan, the scan is repeated during a later 10 cardiac cycle. The longest time during which the heart muscle is substantially stationary is immediately prior to the systolic movement of the heart.

Fig. 5 shows, at curve 26, the Doppler frequency shift of the ultrasound beam centered at the heart muscle. The frequency shift graph represents changes in the velocity of the blood versus time. The curve 26 of course shows changes corresponding to the diastolic and systolic 15 rhythm of the heart. Thus, the muscle velocity is normally increasing during the systolic action of the heart and normally decreasing the time of the diastolic movement of the heart. Thus the diastolic action of the heart will take place at 27 on curve 26 while the systolic movement of the heart occurs at 28 on curve 26. The instances of minimum heart movement, or practically no heart movement takes place at sections 29 and 30 immediately prior to the 20 beginning of the systolic or diastolic movement of the heart, respectively.

As indicated above, the rest period, lasts for 50-200 milliseconds, which is a short period of time for acquiring data. However, during that period of time the coronaries are definitely located and if necessary the scan is repeated to acquire sufficient data to determine the velocity of the blood.

25 Fig. 6 shows how the velocity of the blood at the stenosis section of the blood vessel such as section 24 of blood vessel 14 provides a peak velocity at 34 in Fig. 6. Prior to the stenosis section 36, the velocity is much smaller than the peak velocity at 34 and more or less steady. The same steady state velocity measurement is obtained after the stenosis section shown at 37 in Fig. 7. It should be understood that in practice, the amount of stenosis may vary 30 along the length of the stenosis and that some blockage may be present outside the "stenosis." Thus the regions 34, 36 and 37 do not generally have the smooth form shown in Fig. 6.

The apparatus block diagram showing of Fig. 7 shows the system for simultaneously determining the velocity at multiple gates or volumes in each of the scan sectors so that a

minimal amount of time is actually required for obtaining the vascular blood velocity. The velocity measurement is determinative of whether or not a stenotic condition exists.

More particularly, Fig. 7 shows a Doppler channel 41 for measuring blood velocity. The Doppler channel is shown as comprising a transmitting-receiving unit 42 operating in conjunction with an oscillator, or frequency generator 43. The transmitting portion of the unit 42 transmits pulses of ultrasound waves typically in the order of 2-10 MHz through a transducer, or probe 44. The transducer 44 also acts to receive the signals obtained as sound waves when they are reflected by the walls of the heart and coronaries in the subject 45. The receiving portion of transmitter receiver 42 receives the echoes and transmits them through a demodulator 46 and through a two dimensional imaging channel 47. The demodulator 46 provides in-phase (I) and quadrature (Q) signals. The signals from the demodulator 46 and the two dimensional imaging channel 47 are sent to a processor 48 for image processing. The processed signals are sent to display unit 49 which displays image 51. The displayed image 51 as shown in Fig. 4 generally includes an anatomical image of the sector scanned and encompasses the region of interest 22.

Fig. 4 shows a portion of scan d of Fig. 3 A region of interest 22 is traversed by a plurality of beams such as beams 52, 53 and 54. Coronaries 12-15 are identified. In a preferred embodiment of the invention data is acquired only along (or in the vicinity of) the beams on which coronaries are located. This substantially reduces the amount of data to be acquired and allows for

Along each of the beams, samples are taken at coronaries 12-15. It is at these sample points that the Doppler signal indicates blood flow -that is, blood vessels carrying blood. The received Doppler information at each of the sample points is spectrally processed at processor 45 and the velocity of the blood at the sample point is computed. The results are then displayed as a colored map overlaid on a two dimensional gray scale image. It is in this way that the velocity is determined for each of the sample points. The processing of the flow information performed within the image processor 48 is under the control of controller 61. Controller 61 is shown as having an input interface 62 such as a keyboard, for example, through which instructions or data are inputted.

In the instant method it is generally advisable for the system to be time gated. Accordingly, a heart gate monitor 63 is provided. The monitor causes the transmittal of the Doppler pulses to occur immediately prior to the systolic movement of the heart, when the heart muscle is almost at rest. That enables obtaining data regarding the flow without the

disturbance of the large movements of the heart muscle, which can now be easily filtered out with a high-pass filter, if necessary. The length of the time gate may be made responsive to the amount of data required and the actual time structure of the movement of the heart.

According to one preferred embodiment of the invention, the sector scan is taken during

5 the quiet period of the heart muscle when there is minimum or almost no movement of the heart muscle. The first sector scan determines the location of the coronaries. The scan is repeated on the next heart cycle to determine the actual velocity preferably simultaneously at each sample point on each sector scan by repeating the transmission of the Doppler pulse preferably simultaneously along each of the beams that traverses the coronaries. If necessary a
10 third spectral scan is taken during the next heart cycle until the velocity of the blood in each of the coronaries is determined.

Then the transducer angle is changed so that another sector of the heart is examined. The same procedure is followed until each of the sector scans and velocity measurements of the blood of the coronaries as shown in Fig. 3 is accomplished. Because multiple gates are used,
15 the time required is manageable. During each heart cycle a single sector scan can be accomplished and the blood velocity in all of the coronaries on the single sector measured simultaneously. Alternatively the same sector may be scanned repeatedly until sufficient data is obtained to determine the velocity in each of the coronaries. The scan is then moved to the next sector. This process is repeated until sufficient flow information for the coronaries is
20 acquired to determine whether or not there is indeed a stenosis condition and what is its magnitude.

In both cases, each of the multiple gates are interrogated in parallel to provide the blood flow velocity information in parallel. A typical mode of operation would be that the user pre-selects a region of interest which a system will then investigate. Since the time required for a
25 full spectral Doppler image acquisition of each sector is in the order of 2-4 cardiac cycles, the complete stenosis determination can take place in approximately 6-18 seconds.

In one preferred embodiment of the invention the actual acquisition of data is gated. Alternatively or additionally the analysis of the data is gated to limit it to the points of interest.

The processor 48 preferably also prevents misalignment of the spectral Doppler imaging (SDI) between the scan images and the flow images, that is, the two-dimensional gray scale image and the flow parameters showing on the sector scan image. This is accomplished by the simultaneous generation of both the sector scan image and the Doppler image.

However, another misalignment prevention procedure may be required since repetitions are necessary for each of the sector scans due to the short time available in the time immediately prior to the systolic movement of the heart. This misalignment prevention procedure includes a step of projecting and locking cross-hairs onto the region of interest in the 5 scan sector images. The process of locking each of the sample volume to the specific location within the organ is accomplished using a special image board known to those skilled in the art of image processing as an image TV tracker, shown at 71 in Fig. 8. Such a board automatically identifies outstanding details in the gray scale sector image in each of the different scans and moves the Doppler sample points such that the relative position remained fixed. This also 10 compensates for adverse effects that may be caused by the relative motion between the tissue and the transducer.

Thus, a novel ultrasound diagnostic imagine system wherein stenosis of coronaries can be accurately and reliably determined in a reasonable amount of time has been disclosed. Although preferred embodiments of the apparatus have been described in some detail, it is to 15 be understood that various changes could be made by a person skilled in the art without departing from the spirit and scope of the invention as defined by the attached claims.

What is claimed is:

1. A method for measurement of blood velocity in coronary blood vessels comprising:
determining a time period at which the heart is relatively stationary; and
determining the velocity of blood at one or more points in one or more coronary blood
vessels utilizing ultrasound based method during said determined time period.
2. A method according to claim 1 wherein the ultrasound based method is a non-invasive
method.
- 10 3. A method according to claim 1 or claim 2 wherein the method utilizes Doppler
ultrasound for determining the velocity of the blood.
4. A method according to any of the preceding claims wherein determining a time period
at which the heart is relatively stationary comprises utilizing an ECG measurement.
- 15 5. A method according to any of claims 1-3 wherein determining a time period at which
the heart is relatively stationary comprises utilizing a Doppler ultrasound measurement.
6. A method according to any of the preceding claims wherein the time period at which
20 the heart is relatively stationary is the time period immediately prior to systole.
7. A method according to any of the preceding claims wherein the time period at which
the heart is relatively stationary comprises the time period immediately prior to systole.
- 25 8. A method according to any of the preceding claims wherein the ultrasound system is
gated to acquire data only during said time period at which the heart is relatively stationary.
9. A method according to any of the preceding claims and including:
transmitting ultrasound signals along at least one line which intersects a point at which
30 a coronary is located; and
locating said intersection point along each of the lines at the coronaries and determining
the velocity of blood flow at the intersection point based on signals received from the blood in
the coronaries.

10. A method for measurement of stenosis in a coronary blood vessel comprising:
determining the velocity of the blood at the location of the stenosis utilizing ultrasound;
determining the velocity of the blood at one or more points in the vessel upstream
5 and/or downstream of the stenosis utilizing ultrasound; and
computing the stenosis from the measured velocity at the stenosis and away from the
stenosis.

11. A method according to claim 10 wherein the velocity of the blood is measured
10 according to the method of one of claims 1-9.

12. A method according to claim 10 or claim 11 wherein the location of a stenosis is
determined prior to making said velocity measurements.

15 13. A method according to claim 10 or claim 11 wherein the location of a stenosis is
determined based on said velocity measurements.

14. A method according to any of claims 10-13 and comprising::
scanning the heart with ultrasound;
20 acquiring a plurality of ultrasound sector scan images of the heart at different locations
in the heart;
examining each of the sector scan images using spectral Doppler signals to locate
multiple coronaries;
gating the spectral Doppler signals to occur when the heart is at relative rest; and
25 determining the velocity of blood flow in the coronaries in each of the sector scan
images by using the spectral Doppler signals.

15. A method according to claim 14 including:
locating multiple coronaries in each of the sectors;
30 acquiring as much velocity information as possible during the gating period;
moving to the next sector to locate the multiple coronaries and to determine as much
blood velocity information as possible during the gating period; and

returning to each of the sectors to complete the determination of the velocity information as necessary.

16. A method according to claim 14 or claim 15 and including determining the velocity of
5 blood flow in each coronary in each sector before moving on to the next sector for measurements.

17. A method according to any of claims 14-16 wherein examining each of the sector scan images to locate coronaries includes:

10 traversing selected sectors by a plurality of beams for determining where along each of the beams multiple coronaries are located; and

simultaneously Doppler scanning each of the multiple coronaries in parallel to provide the blood flow velocity information in parallel with the sector scan.

15 18. A method according to any of claims 14-17 and including preventing misalignment between the sector scan images and flow images.

19. A method according to claim 18 wherein preventing misalignment includes the simultaneous generation of both the sector scan images and the Doppler images.

20 20. A method according to claim 19 wherein preventing misalignment comprises:
projecting a tracking element onto the coronaries, and
locking the tracking element onto the coronaries in the sector scan images.

25 21. A method according to claim 20 wherein locking comprises using a TV tracker.

22. Apparatus for measurement of blood velocity in coronary blood vessels comprising:
a controller which determines a time period at which the heart is relatively stationary;
and

30 an ultrasonic measurement system which determines the velocity of blood at one or more points in one or more coronary blood vessels during said determined time period.

23. Apparatus according to claim 22 wherein the ultrasonic measurement system is a non-invasive system.

24. Apparatus according to claim 22 or claim 23 wherein the ultrasonic measurement
5 system is a Doppler ultrasound system.

25. Apparatus according to any of claims 22-24 wherein the controller comprises an ECG monitor which supplies electrical signals indicative of the motion of the heart.

10 26. Apparatus according to any of claims 22-24 wherein the controller utilizes a Doppler ultrasound measurement in determining the time period.

27. Apparatus according to any of claims 22-26 wherein the time period at which the heart is relatively stationary is the time period immediately prior to systole.

15

28. Apparatus method according to any of claims 22-26 wherein the time period at which the heart is relatively stationary is the time period immediately prior to systole.

29. Apparatus according to any of claims 22-28 wherein the ultrasonic measuring system is
20 gated to acquire data only during said time period at which the heart is relatively stationary.

30. Apparatus according to any of claims 22-29 wherein:

 said ultrasonic measurement system transmits ultrasound signals along at least one line which intersects a point at which a coronary is located; and

25 said controller locates said intersection point along each of the lines at the coronaries and determines the velocity of blood flow at the intersection point based on signals received from the blood in the coronaries.

31. Apparatus for measurement of stenosis in a coronary blood vessel comprising:

30 an ultrasonic measurement system which measures the velocity of the blood at the location of the stenosis and determines the velocity of the blood at one or more points in the vessel upstream and/or downstream of the stenosis; and

a controller which computes the severity of the stenosis from the measured velocity at the stenosis and away from the stenosis.

32. Apparatus according to claim 31 wherein the ultrasonic measurement system and the
5 controller comprise the apparatus of any of claims 22-30.

33. Apparatus according to claim 31 or claim 32 wherein the ultrasonic measurement system and the controller utilize the method of any of claims 10-21.

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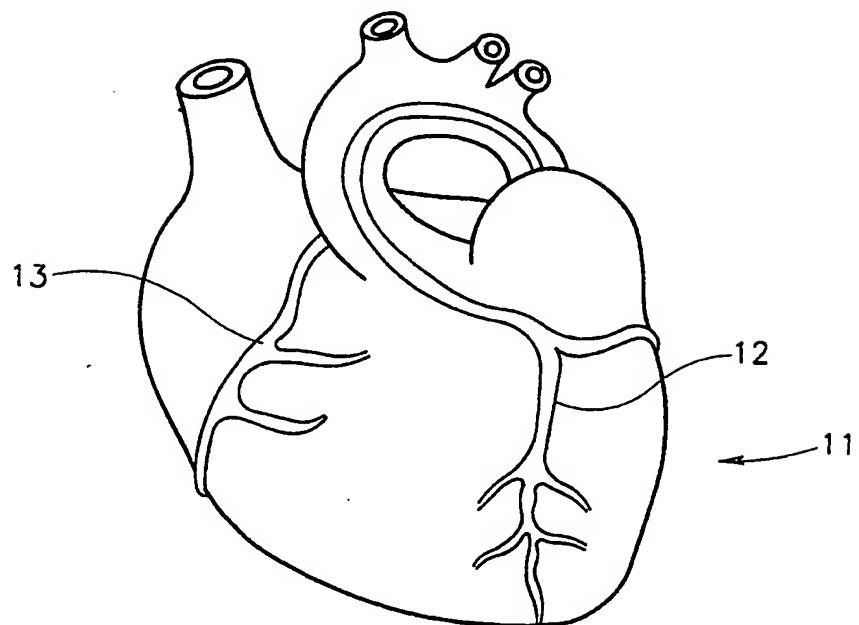


FIG. 1

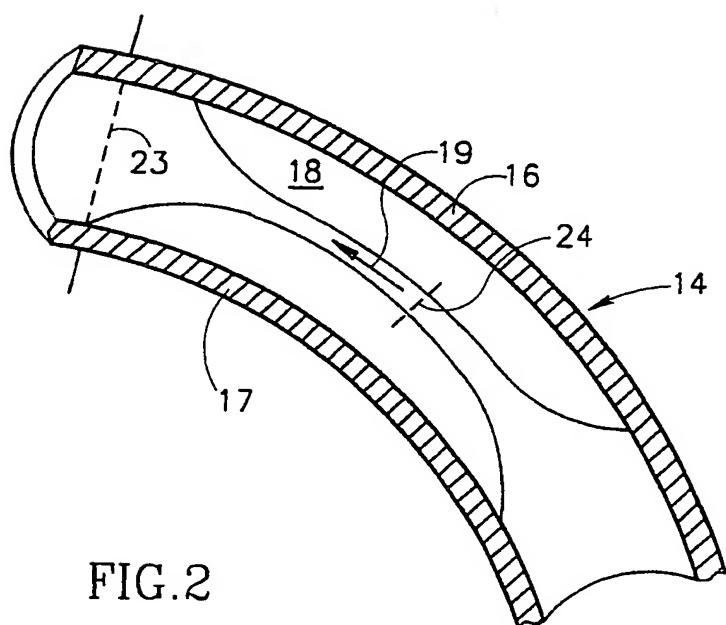


FIG. 2

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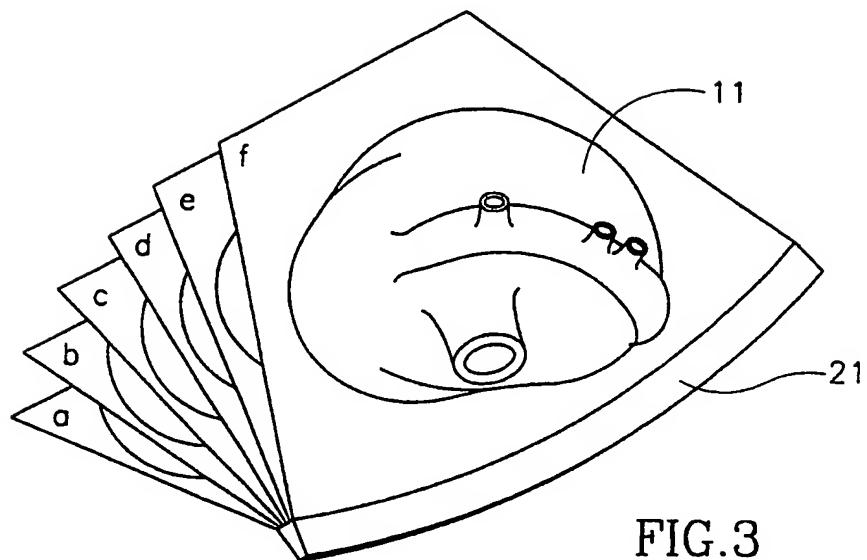


FIG.3

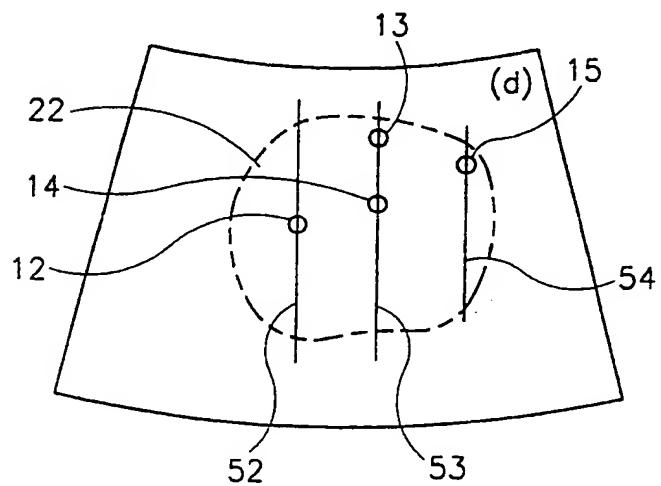


FIG.4

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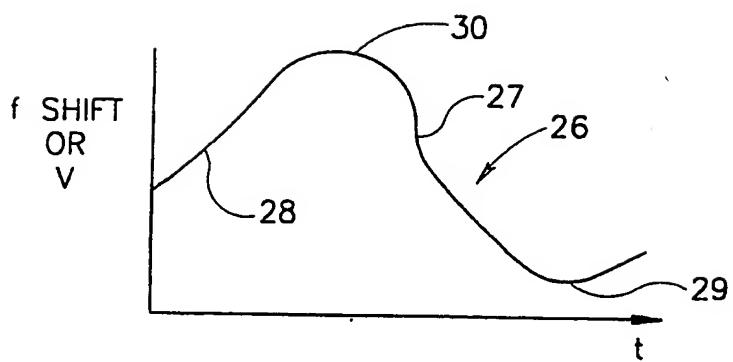


FIG.5

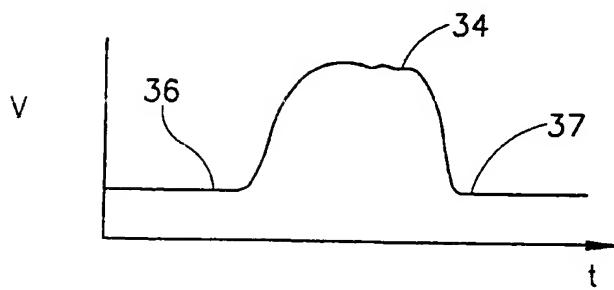


FIG.6

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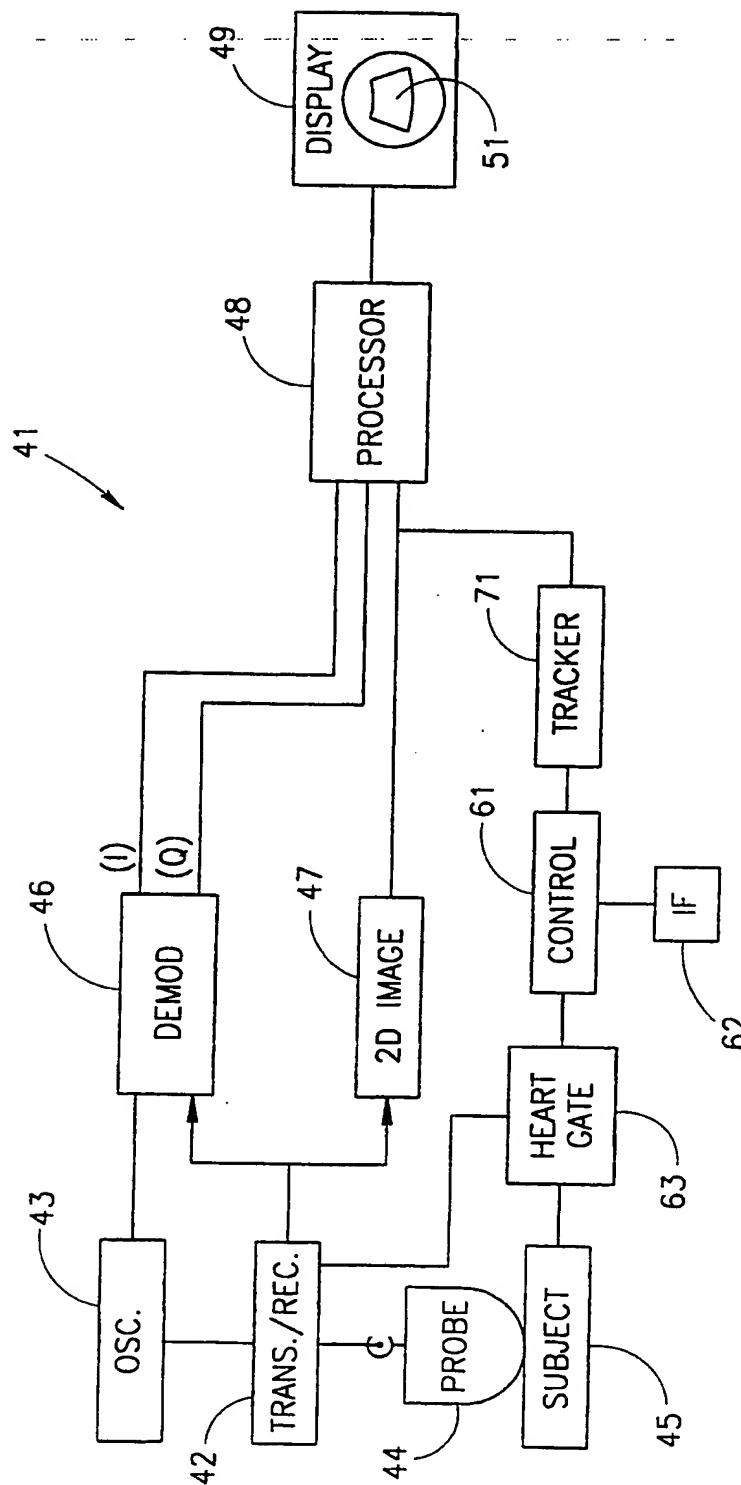


FIG. 7

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IL 97/00392

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B8/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 383 463 A (FRIEDMAN ZVI) 24 January 1995 see column 2, line 19 - line 58 see column 3, line 3 - column 5, line 3; tables 1-3 & US 5 419 332 A cited in the application ---	1-5, 22-26
A	US 5 327 893 A (SAVIC MICHAEL) 12 July 1994 see column 5, line 5 - column 6, line 26 see column 6, line 58 - column 7, line 19 see column 11, line 19 - column 12, line 62; tables 1-8 ---	1-5,10, 13,22-26
A	FR 2 591 884 A (WASHINGTON RES FOUND) 26 June 1987 see page 55, line 2 - line 35 -----	10-13,31

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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Date of the actual completion of the international search

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Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Internal Application No	
PCT/IL 97/00392	

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5383463 A	24-01-95	US 5419332 A	30-05-95
US 5327893 A	12-07-94	NONE	
FR 2591884 A	26-06-87	US 4770184 A DE 3643162 A JP 62164441 A	13-09-88 19-06-87 21-07-87